

REMARKS

Applicant respectfully requests reconsideration. Claims 1-39 were previously pending in this application, with claims 1-38 having been withdrawn. By this amendment, Applicant is canceling withdrawn claims 1-38 without prejudice or disclaimer. Claim 39 is currently amended. New claims 40 and 41 have been added. As a result, claims 39-41 remain pending for examination, with claim 39 being an independent claim. No new matter has been added.

Claim 39 is currently amended to specify that the multimeric compound is a homo-multimeric anti-PSGL-1 antibody. Support for this amendment can be found, for example, at page 5, lines 1-5, in the specification.

New claim 40 specifies that the homo-multimeric anti-PSGL-1 antibody of claim 39 is a chimeric anti-PSGL-1 antibody. Support for this claim can be found, for example, at page 14, lines 10-12, and page 15, lines 8-15, in the specification.

New claim 41 specifies that the homo-multimeric anti-PSGL-1 antibody of claim 39 is a humanized anti-PSGL-1 antibody. Support for this claim can be found, for example, at page 14, lines 10-12, and page 15, lines 28-30, in the specification.

Priority Objection

The Examiner rejected the instant application's claim to priority under 35 U.S.C. § 120 to U.S. Patent Application Serial No. 10/051,497 as well as to U.S. Provisional Application Serial No. 60/310,196 under 35 U.S.C. § 119(e), alleging that these previous applications do not appear to provide sufficient written description for the claimed subject matter of the present application. Applicant respectfully disagrees.

U.S. Patent Application Serial No. 10/051,497 includes the following passage found at page 5 of that application:

In another aspect, the invention features a kit containing: a compound that binds to PSGL-1 on the surface of a T cell, wherein the binding of the compound to PSGL-1 on the surface of the T cell induces a signal transduction pathway that results in the death of the T cell; and instructions for use of the compound to treat

autoimmunity, transplant rejection, an allergic condition, or a T cell cancer. In other embodiments, the kit includes instructions for use to treat any disease or disorder described herein.

A similar passage can be found in the paragraph bridging pages 8-9 of the instant specification.

Original claim 37 of U.S. Patent Application Serial No. 10/051,497 is as follows:

37. A kit comprising: a compound that binds to PSGL-1 on the surface of a T cell, wherein the binding of the compound to PSGL-1 on the surface of the T cell induces a signal transduction pathway that results in the death of the T cell; and instructions for use of the compound to treat autoimmunity, transplant rejection, an allergic condition, or a T cell cancer.

The compounds referred to in the preceding passages from U.S. Patent Application Serial No. 10/051,497 are clearly disclosed throughout that application to include antibodies that specifically bind PSGL-1.

U.S. Patent Application Serial No. 10/051,497 further includes the following passages found at pages 10-11 of that application:

Antibodies within the invention therefore include polyclonal antibodies and, in addition, monoclonal antibodies, humanized or chimeric antibodies, single chain antibodies, Fab fragments, F(ab')² fragments, and molecules produced using a Fab expression library. ...

In addition, techniques developed for the production of "chimeric antibodies" (Morrison et al., Proc Natl Acad Sci USA 81:6851 [1984]; Neuberger et al., Nature 312:604 [1984]; Takeda et al., Nature 314:452 [1984]) by splicing the genes from a mouse antibody molecule of appropriate antigen specificity together with genes from a human antibody molecule of appropriate biological activity can be used. A chimeric antibody is a molecule in which different portions are derived from different animal species, such as those having a variable region derived from a murine monoclonal antibody and a human immunoglobulin constant region. ...

Antibodies can be humanized by methods known in the art. For example, monoclonal antibodies with a desired binding specificity can be commercially humanized (Scotgene, Scotland; Oxford Molecular, Palo Alto, Calif.).

Applicant asserts that the subject matter of instant claim 39, as well as of instant claims 40-41, is disclosed at least in U.S. Patent Application Serial No. 10/051,497 in sufficient detail as to demonstrate that Applicant was in possession of the claimed invention at least as early as the filing date of U.S. Patent Application Serial No. 10/051,497. Accordingly, Applicant asserts that the instant claims should be accorded an effective filing date at least as early as the filing date of claimed priority document U.S. Patent Application Serial No. 10/051,497, i.e., January 18, 2002.

Objections to the Specification

The Examiner objected to the title and requested that the specification as filed be proofread for spelling errors and trademark names and appropriate corrections be made.

As to the title, Applicant respectfully suggests the title can be amended to read as APOPTOSIS-INDUCING ANTI-PSGL-1 ANTIBODY COMPOSITIONS FOR THERAPEUTIC USE.

As to proofreading and use of trademarks, Applicant has made amendments to the specification as required by the Examiner.

Amendments to the paragraph bridging pages 31-32 include correction of two obvious typographical errors in which “TAB4”, which the rest of the specification makes abundantly clear refers to an antibody, was erroneously written in place of “TAIP”, which the rest of the specification makes abundantly clear refers to a protein recognized by TAB4. See, for example, page 24, lines 11-14 of the specification.

Accordingly, withdrawal of this objection is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner rejected claim 39 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2004/0002450 to Lazarovits et al. (“Lazarovits”) and/or U.S. Patent Publication No. 2004/0001839 to Levanon et al. (“Levanon”) in view of U.S. Patent No.

6,348,581 to Anderson et al. (“Anderson”) and/or U.S. Patent No. 6,884,619 to Hockfield et al. (“Hockfield”). Lazarovits and Levanon are related applications, filed on the same date and both claiming priority from a single provisional application, with largely identical disclosures. These two pre-grant publications were cited by the Examiner principally for their disclosure of antibodies KPL1, Y1, and Y17 and uses thereof in connection with inflammation, autoimmune disease, and certain cancers. Anderson and Hockfield were cited by the Examiner principally for their disclosure of kits that include therapeutic antibodies. The antibodies disclosed in Anderson and in Hockfield are directed to antigens which are distinct from PSGL-1. For reasons stated below, Applicant respectfully traverses.

An invention that would have been obvious to a person of ordinary skill at the time of the invention is not patentable under 35 U.S.C. 103(a). Obviousness is a question of law based on underlying factual inquiries. The Supreme Court has set out the framework for the objective analysis for determining obviousness in *Graham v. John Deere Co. (Graham)*, 383 U.S. 1, 148 USPQ 459 (1966), recently reaffirmed in *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. __, 82 USPQ2d 1385 (2007). The factual inquiries informing this analysis are (A) determining the scope and content of the prior art; (B) ascertaining the differences between the claimed invention and the prior art; and (C) resolving the level of ordinary skill in the pertinent art. *Graham*, 383 U.S. 1, 148 USPQ 459 (1966). Objective evidence, sometimes referred to as “secondary considerations,” including commercial success, long-felt but unsolved needs, failure of others, and unexpected results, can supplement the factual inquiries informing this analysis. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR* 550 U.S. __, __, 82 USPQ2d 1385, 1396 (2007). MPEP 2143.01.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. MPEP 2142. Significantly, any *prima facie* case must account for all features of the claimed invention. *KSR* 550 U.S. __, 82 USPQ2d 1385 (2007).

Applicant respectfully asserts that the Examiner has not made a *prima facie* case for obviousness because he has not provided any evidence to support the claimed feature “wherein the binding of the multimeric compound to the at least two PSGL-1 proteins on the surface of the T cell induces a signal transduction pathway that results in death of the T cell.” Neither Lazarovits nor Levanon makes any teaching in respect of the ability of KPL1, Y1, or Y17 to induce a signal transduction pathway that results in the death of the T cell. Similarly, neither Anderson nor Hockfield makes any teaching in respect of this claim element. The references, even if combined as suggested by the Examiner, do not teach or suggest all the recited features of the claimed invention and therefore do not render obvious the claimed invention. Furthermore, there is nothing in any of these references to lead a person skilled in the relevant art to think to look to see if KPL1, Y1, or Y17 can induce a signal transduction pathway that results in the death of the T cell.

Additionally, it should be noted that the disclosed antibody KPL1 is a murine anti-human PSGL-1 monoclonal antibody that does not satisfy both features (i) and (ii) of claim 39. That is, no polypeptide of KPL1 comprises both (i) a binding domain that binds to PSGL-1 and (ii) a heterologous amino acid sequence. KPL1 disclosed in Lazarovits and Levanon is thus outside the scope of the instant claimed invention, and the Examiner has not articulated any reason for modifying KPL1 such that it might satisfy both features (i) and (ii) of claim 39.

Accordingly, Applicant asserts that the Examiner has not made a *prima facie* case of obviousness and respectfully requests that the Examiner withdraw the rejection of claim 39 under 35 U.S.C. §103(a).

Provisional Double Patenting Rejection

The Examiner provisionally rejected claim 39 under the judicially created doctrine of obviousness-type double patenting over claims 9-10 of copending U.S. Patent Application Serial No. 11/125,837 in view of Lazarovits (*supra*) and/or Levanon (*supra*), together with Anderson (*supra*) and/or Hockfield (*supra*). At this time Applicant would merely point out that Lazarovits, Levanon, Anderson, and Hockfield do not teach or suggest features of instant claim 39, as

explained above. Otherwise Applicant requests that this provisional rejection be withdrawn or else held in abeyance until such time as one or more of the specified claims is allowed.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. A0871.70001US00.

Dated: April 29, 2008

Respectfully submitted,

By 
Alan W. Steele, M.D., Ph.D.
Registration No.: 45,128
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
(617) 646-8000